

## **FOOD SAFETY AND INSPECTION SERVICE**

### **Submitted for the Record**

#### **Statement of Dr. Merle Pierson, Acting Under Secretary for Food Safety Before the Subcommittee on Agriculture, Rural Development, and Related Agencies**

Mr. Chairman and Members of the Subcommittee, I am pleased to appear before you today to discuss the status of the Food Safety and Inspection Service (FSIS) programs and the fiscal year (FY) 2006 budget for food safety within the U.S. Department of Agriculture (USDA). I am Dr. Merle Pierson, Acting Under Secretary for Food Safety. With me today is Dr. Barbara Masters, Acting Administrator of FSIS.

As we begin another new year at USDA, I am proud to emphasize several areas where we have used science based policies to effectively protect the health and well being of millions of consumers worldwide. These successes would not have been possible without the resources you have so generously given to us. I also will share with you our goals for this year, and will conclude with a discussion of the FY 2006 budget request.

The crux of our public health challenge centers on combating biological, chemical, and physical hazards that range from the easily understood to those that evolve and present new and complex challenges. Thus, we must not only rely on existing knowledge and strategies for food safety, but also continue to introduce and evaluate new approaches. For me, as someone who has spent their entire career as a food scientist, I am particularly proud of the work our office and FSIS has

done in developing science based policies to improve the safety and security of the U.S. meat, poultry, and egg products supply.

### **Evaluating the Effectiveness of the 2004 Vision**

While there are many approaches to measuring success, we looked at indicators related to public health outcomes and pathogen reduction. Such an evaluation is essential in determining the success of our strategies and developing new ways to combat threats to public health. In our high-speed, fast-food world, it can be difficult for some to understand that successful science is not immediate gratification and it is not easily measured. But over time, positive results, or I should say, dramatic declines in foodborne illnesses or incidence of pathogens in products, show that our risk based approach is working.

### **Breaking the Cycle of Multi-Million Pound Recalls**

One indication of our progress is that we have seen a break in the annual cycle of multi-million pound recalls. Through the use of risk assessments, working with partners along the farm-to-table continuum, and basing our policies on sound science, we have been able to break this vicious cycle. I will illustrate this by discussing our *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* policies.

After a comprehensive risk assessment on *E. coli* O157:H7 was completed, we developed additional strategies to eliminate this pathogen in beef establishments. We required all of the approximately 2,900 beef slaughter and processing establishments to reassess their Hazard Analysis and Critical Control Point (HACCP) plans relative to the potential presence and control

of *E. coli* O157:H7 in raw beef. Then our scientifically trained personnel conducted the first-ever comprehensive reviews of the reassessed HACCP plans.

I believe this type of forward thinking initiated by USDA/FSIS will continue to contribute to the dramatic improvements we have been seeing. For instance, let's take a look at results from our microbiological surveillance testing program for *E. coli* O157:H7 over the past four years.

- In CY 2001, our testing program yielded 59 positive results out of 7,010 samples;
- In CY 2002, there were 55 positive results from 7,025 samples;
- In CY 2003, there were 20 positives out of 6,584 samples; and
- In CY 2004, there were only 14 positives out of 8,010 samples.

The effectiveness of using sound science is also evident when we look at *Listeria monocytogenes*. Our 2003 interim final rule on control of *Listeria monocytogenes* in ready-to-eat (RTE) meat and poultry products, based on a thorough risk assessment, outlined three strategies that an establishment could choose from to control the pathogen depending on its product(s) and the environment in which it operates: Alternative 1, provides for a combination of a post-lethality treatment and a growth-suppressing agent or process; Alternative 2, provides for either a post-lethality treatment or a growth-suppressing agent or process; and Alternative 3, relies on sanitation as the primary mitigation. In January 2005, FSIS revised its sampling verification procedures so that more product samples are collected when an establishment relies solely on sanitation practices for *Listeria monocytogenes* control, while fewer samples are analyzed in situations where an establishment has more aggressive process control measures and interventions.

In 2003, we released data that showed a 25 percent drop in the percentage of positive *Lm* regulatory samples from the year before, and a 70 percent decline compared with years prior to the implementation of HACCP.

Our science based initiatives, including those used to counter *E. coli* O157:H7, have played a significant role in also reducing the prevalence of *Salmonella* in raw meat regulatory samples. If we look at the percentage of regulatory samples positive for *Salmonella* from our scientific HACCP verification testing program, we see an overall aggregate downward trend from 1998 through 2003. *Salmonella* presence in raw meat and poultry regulatory samples has dropped substantially over the past six years. Out of the number of regulatory samples collected and analyzed by FSIS in 2003, 3.8 percent tested positive for *Salmonella*, as compared with 4.29 percent in 2002, and 10.65 percent in 1998.

While the regulatory prevalence of *Salmonella* across all seven product categories tested continued to decrease in 2003, we are concerned that the percentage of positive *Salmonella* tests increased slightly in three poultry categories. FSIS has been examining *Salmonella* testing data from 1998 to the present in order to clearly identify those plants displaying negative performance trends. Enforcement Investigations and Analysis Officers can now conduct in-depth HACCP and sanitation verification reviews at those facilities to help ensure that this increase does not continue. FSIS compares regulatory testing results to pre-HACCP baseline prevalence to provide context to the yearly data. These 2003 numbers are still under the standard for the aggregate data, but FSIS is working aggressively to reverse the upward trend.

Let me also add that when there has been foodborne illness, FSIS aggressively explores both epidemiological links to products from individual establishments as well as conducts a food safety assessment to determine whether or not insanitary conditions exist. If the epidemiological link is found or insanitary conditions exist, appropriate regulatory enforcement action is taken.

I have provided a brief overview of some of the measures I believe have broken the annual cycle of multi-million pound recalls. I would like to mention trends we are seeing in recall data.

In the late-1990s, the number of recalls had been increasing steadily with at least one multi-million pound recall being conducted every year; however, this trend has dramatically changed in the past two years.

- In 1997, there were 27 recalls;
- Followed by 44 recalls in 1998;
- 58 recalls in 1999;
- 76 recalls in 2000;
- 87 recalls in 2001; and
- Reaching an all-time high of 113 recalls in 2002.

After we implemented the science based policies I mentioned earlier, we saw a dramatic decline in recalls, culminating in a reduction of nearly 18 percent in the number of pathogen-related recalls, from 28 in 2003, to 23 in 2004. While this is certainly good news, we still have areas of concern. One of the areas of concern is an increasing trend in the percentage of recalls triggered

by undeclared allergens. This is a troubling development. We have alerted industry of our concerns and are currently taking case-by-case action and are looking at broader policies to address it industry-wide.

Perhaps even more dramatic is the fact that 2004 marked the second year in a row that we did not have a multi-million pound recall of meat or poultry in the United States. The decline in the number of recalls is just one of several indicators that highlight the dramatic improvements that can be achieved in our food safety system when government, industry, consumers, and academia work together and use science as a guide. Another measure of progress came from a Gallup poll released this past August. It found that more than 85 percent of Americans are confident in the Federal government's ability to protect our food supply.

### **Declining Foodborne Illnesses**

This news is encouraging, but the most significant measure of public health impact is the annual report published by the Center for Disease Control and Prevention (CDC) last spring in which they reported significant declines from 1996 to 2003 in illnesses caused by *E. coli* O157:H7, *Salmonella*, *Campylobacter*, and *Yersinia*.

Specifically to the products USDA regulates, the CDC reported that illnesses caused by *Salmonella Typhimurium*, typically associated with meat and poultry, decreased by 38 percent from 1996 to 2003. Human illnesses caused by *E. coli* O157:H7, often associated with ground beef, declined 42 percent from 1996 to 2003. The decrease in *E. coli* O157:H7 infections occurred primarily during 2002- 2003.

The CDC attributes the changes in the incidence of these infections in part to the control measures implemented by government and industry leaders, enhanced food-safety education efforts, and increased attention by consumer groups and the media. We are hopeful that if we continue on our current course, this reduction will not be just for one year, but will continue from now until we have achieved the greatest reduction possible in the illnesses caused by these pathogens.

### **Bovine Spongiform Encephalopathy**

Science based policies and recalls are two tangible methods that external parties see USDA conducting to protect public health. However, a significant amount of public health protection comes from the extensive strategic planning efforts to improve our systems and infrastructure that are not as easily recognized. I mention this in reference to the first case of bovine spongiform encephalopathy (BSE) detected in the United States in December 2003.

The December 23, 2003, detection of a BSE positive cow, originally from Canada, at a slaughter operation in Washington State could be seen by many as a precursor to the implementation of our BSE measures. However, we had completed an extensive amount of groundwork on FSIS' four BSE measures before USDA's major policy announcements on December 30, 2003. Our swift actions were unprecedented. The process for publishing FSIS' interim final rule on BSE normally would have taken several months; however, with the prior strategic planning this normally daunting task was achieved in less than two weeks, and was done at the time with an eye for protecting public health. Our BSE regulations add a significant level of protection to an

already robust food safety system. FSIS' BSE related interim final rules will be published as final rules following an analysis of the more than 22,000 comments received on the interim final rules and the BSE Advance Notice of Proposed Rulemaking (ANPR) as well as completion of the Animal and Plant Health Inspection Service (APHIS) enhanced BSE surveillance program and the Harvard BSE risk reassessment.

### **Training for the Mission**

Strong, science-based regulations and policies are merely words on paper without personnel trained to carry them out. I would like to thank the Congress, and this Subcommittee in particular, for the record level of funding it has provided us in the area of training and education. Each training accomplishment directly correlates to improvements in the safety and security of the U.S. meat, poultry, and egg supply. We are extremely proud of our efforts in this area and I would like to share some of our successes with you today.

A large segment of our inspection program personnel is receiving intensive training in sanitation procedures and Hazard Analysis and Critical Control Point (HACCP) system principals, based on the type of products produced at the establishments where the inspectors are assigned. We expect to have this segment of our workforce fully trained by the end of the current fiscal year. In 2003, FSIS inaugurated Food Safety Regulatory Essentials (FSRE) training, which was designed to better equip inspection personnel in verifying an establishment's HACCP food safety system. All participants receive training in the fundamentals of inspection, covering HACCP, the Rules of Practice, Sanitation Performance Standards, and Sanitation Standard Operating Procedures. This program also provides food safety training based on the types of products



being produced at the establishments where inspectors are assigned. In FY 2004, 1,700 individuals received the Agency's FSRE training, more than doubling the amount of students trained in FY 2003.

FSIS has also initiated a comprehensive multi-year training and education effort designed to ensure that every FSIS employee fully understands their role in preventing or responding to an attack on the food supply. To date, over 5,000 employees have received food security training. The Law Enforcement Academic Research Network (LEARN), which is carrying out the training, has stated that this effort is unparalleled in the Federal sector since training is being provided to such a broad base of our employees.

Furthermore, FSIS has successfully launched training for newly hired Public Health Veterinarians (PHVs) and for newly hired food inspectors. We are also going back to train "new hires" to ensure that employees who did not initially receive this training are now fully equipped with the latest scientific knowledge. In addition, we now require entering Consumer Safety Inspectors to undergo and pass FSRE training. We are also in the process of implementing policies to require passage of mandatory training courses for entering Enforcement Investigations and Analysis Officers (EIAOs) and for PHVs. Specifically in 2005, we plan to provide training for 1,200 food inspectors, 400 PHVs, 200 EIAOs, 75 import inspectors, and 40 front line supervisors. We also plan to provide FSRE training for 1,400 Agency personnel. I also would like to note that we offer seats in our workforce training courses to State inspection personnel.

These numbers are impressive, but what is even more meaningful are the systematic changes at FSIS that this training effort has brought. Our workforce is becoming the most scientifically trained in the world. While we know these are merely the first steps, and that this knowledge still needs to be extended to all our employees, we have embarked on a path that will bring added protections to public health for generations to come.

### **Food Security**

Ensuring the security of FSIS inspected products is indeed an awesome responsibility, and it is one which FSIS and its predecessor agencies have been equipped to handle for almost a century. Over the past several years, we have strengthened our focus on both intentional and unintentional contamination by conducting risk and vulnerability assessments. Specifically for food security, vulnerability assessments have provided a solid foundation from which we have launched many important initiatives to safeguard our food supply from any intentional threats.

We have found these assessments are very powerful risk management tools that can be used to develop strategies and policies that reduce or eliminate the potential risk at vulnerable points along the farm-to-table continuum. It is difficult to manage a threat when we are unsure of its scope, so it was especially important to take a broad look when developing the risk assessments.

The vulnerability assessments we conducted provided us the vital data regarding risks in our system that otherwise would not have been as apparent to us if we had not conducted them. If we had made food security decisions without performing vulnerability assessments, it would have been akin to aiming at a target in the dark without night-vision goggles. We would have

had no idea if we had hit our mark. And when that mark is the security of the food on American tables, accuracy is crucial.

What we gleaned from these vulnerability assessments helped us develop more effective intervention strategies, especially when it comes to surveillance and incident response plans.

The assessments allowed us to rank food products and potential contaminating agents in order of highest concern. By using this risk based ranking, during periods of heightened awareness, our laboratories can examine samples for threat agents posing the greatest risk as identified in our vulnerability assessments.

## **Communications**

Public health benefits from our efforts in training and in food security cannot be fully realized without a comprehensive and cohesive communications infrastructure. For example, the highly trained import inspector may only have a few critical moments to alert his colleagues across the country in the event of a food security incident. Without “real time” information, inspectors in Montana may not know to stop a suspect cargo. In an emergency, the American public cannot afford for precious seconds to be lost while information slowly synchronizes over outdated modems. We are maximizing the effectiveness of our resources in this area and continue to work towards seamless integration, both internally and with our other food safety partners.

To be a successful public health Agency, our employees need the right information to do their jobs. This information needs to be communicated quickly and accurately, ensuring public health will be protected. Data that is delayed is less useful and in extreme circumstances could have

limited value because it is too late and could threaten the safety of our meat, poultry, and egg product supply. It is vitally important that the Agency continue to receive the necessary funds to develop and upgrade its information technology systems, which will improve efficiency and enhance communication among all FSIS employees. For FSIS, the use of databases to track inspection program tasks is essential for food safety verification. It is a vital communication resource whereby inspectors can enter information about their daily food safety, security, and humane handling verification duties. Because of our public health mission, real-time information and connectivity is vital, especially between key sites for our inspection program personnel. This is particularly important because FSIS has a geographically dispersed workforce. Managers in the field and at headquarters must make crucial management decisions based on tracking and analyzing information from their employees and the establishments they regulate. A rapid exchange of information with the field is critical for FSIS supervisors and managers to make better informed decisions on food safety and security issues, thus better protecting public health. We seek your continued support in this area.

### **Humane Handling and Slaughter Activities**

FSIS continues to ensure compliance with the Humane Methods of Slaughter Act (HMSA) in livestock slaughter establishments that operate under Federal inspection. As part of their routine, ongoing and continuous inspection and enforcement duties, all FSIS inspection personnel are expected to take appropriate action, including suspending operations, if appropriate, of a livestock slaughter establishment if they observe any violations of HMSA. Further, all FSIS inspection personnel are trained and held accountable for enforcing HMSA during the slaughter process.

District Veterinary Medical Specialists (DVMSs) provide technical expertise and oversight for HMSA-related activities, and ensure that humane handling and slaughter activities and enforcement are handled consistently by inspection program personnel. The Agency's DVMSs and Deputy District Managers meet periodically as a group at the Technical Service Center in Omaha, Nebraska, to correlate on humane enforcement issues, and, in fact, one such meeting was just held in March 2005.

FSIS has continued to refine humane handling verification and tracking procedures for inspection personnel. On February 18, 2005, the Agency issued FSIS Notice 12-05, to provide inspection personnel with additional information for humane handling and slaughter verification activities related to animal stunning and procedures for checking for conscious animals.

### **Future Initiatives**

While we have made considerable progress, I stress that there is more to be done to decrease the number of foodborne illnesses in the United States even further. USDA is committed to further improving public health through food safety and security through our continuing programs such as those I have described as well as several science-based initiatives I would like to mention.

#### Enhanced Data Integration

In order to better protect public health, our first initiative is to anticipate and predict food safety risks through enhanced data integration. One significant way to accomplish this is through the analysis of FSIS regulatory sampling data, as well as other sources of data, including baseline

studies, in order to detect trends and identify connections between persistence, prevalence, and other factors such as practices employed by plants, seasonal variations, and establishment size.

However, there is a missing link here. FSIS would need access to industry data. Including data collected by the establishment would add robustness to FSIS' information and improve the quality and validity of decisions that are made. Ensuring the availability of data to FSIS from industry, academia, States, consumers, and others will be necessary to help us protect food safety risks. One way to accomplish this may be through the establishment of a repository to provide data integrity and confidentiality. We are examining this initiative and will have more details available in the near future.

#### Associate Program Outcomes to Public Health Surveillance Data

Our next initiative is to improve the association of program outcomes to public health surveillance data. We are working closely with the CDC and the Department of Health and Human Services' Food and Drug Administration (HHS-FDA) to improve our ability to link foodborne illness estimates with different food groups. Data on foodborne illnesses due to specific pathogens needs to be connected with prevalence data for different pathogens in specific foods.

The Foodborne Diseases Active Surveillance Network, or FoodNet, allows FSIS and our Federal, State, and local food safety partners to integrate this data by determining the burden of foodborne disease, monitoring foodborne disease trends, and determining the extent of foodborne diseases attributable to specific foods. By comparing and contrasting the

characteristics of pathogens recovered from food samples with those recovered from foodborne illness patients, we are able to improve our ability to link foodborne illness data with specific foods.

As indicated from my overview earlier of our accomplishments, USDA and its partners have made significant and dramatic improvements in food safety since the implementation of HACCP as the driving component of FSIS' enforcement of the Federal Meat Inspection Act and the Poultry Products Inspection Act. The number of foodborne illnesses attributed to FSIS-regulated products has declined markedly as have the rates of contamination in regulatory samples. However, the implementation of our new science-based initiatives is critical for us to strengthen our food safety infrastructure even further. Enhancing data integration and improving the association of program outcomes to public health surveillance data will provide the additional, essential tools we need to improve public health.

### **FY 2006 Budget Request**

I appreciate having the opportunity to discuss a number of FSIS' accomplishments with you.

Now, I would like to present an overview of the FY 2006 budget request for FSIS.

Implementation of these budget initiatives is imperative to helping us attain FSIS' public health mission. In FY 2006, FSIS is requesting an appropriation of \$849.7 million, a net increase of about \$32.5 million from the enacted level for FY 2005, which includes \$139 million to be derived from proposed new user fees from the industry.

### Food and Agriculture Defense Initiative

The FY 2006 budget also requests an increase of \$19.5 million for FSIS to support a food and agriculture defense initiative in partnership with other USDA agencies, the Department of Health and Human Services and the Department of Homeland Security (DHS). Food contamination and animal and plant diseases can have catastrophic effects on human health and the economy. The three Federal departments involved are working together to create a comprehensive food and agriculture policy that will improve the government's ability to respond to the dangers of disease, pests, and poisons, whether natural or intentionally introduced. Our food and agriculture defense initiative has five components:

- The Food Emergency Response Network (FERN);
- Data systems to support the FERN;
- Enhancing FSIS laboratory capabilities;
- Biosurveillance; and
- Follow-up bio-security training.

For FERN we are seeking an increase of \$13 million; for FERN data systems we are asking for an increase of \$2.5 million; for enhancing laboratory capabilities we are requesting \$2.5 million; for biosurveillance we are requesting an increase of \$417,000; and for bio-security training we are seeking an increase of \$1 million.

The first component of the food and agriculture defense initiative is FERN, a coordinated initiative between FSIS and the Department of Health and Human Services' Food and Drug



Administration (FDA) to develop an integrated network of federal, state, and local laboratories. FERN is an integrated laboratory network capable of providing ongoing surveillance and monitoring of the food supply, as well as conducting the extensive testing necessary in the event of a terrorist attack on the food supply. The FSIS FY 2006 budget request for FERN seeks an increase of \$13 million from FY 2005 which will enable the Agency to manage, maintain, and expand on the existing group of FERN labs. These funds will improve the Agency's ability to handle the greatly increased number of samples that would be required to be tested in the event of a terrorist attack on the meat, poultry or egg products supply. These State and local laboratories in the FERN network would play an essential role in conducting this expanded testing.

The second and third components of the food and agriculture defense initiative provide further support to FERN. The electronic laboratory exchange network (eLEXNET) is a national, web-based, electronic data reporting system that allows analytical laboratories to rapidly report and exchange standardized data. The FY 2006 budget request would provide funding needed to make eLEXNET available to additional FERN and other food-testing laboratories nationwide. In turn, the budget request would enhance FSIS' laboratory capabilities in order to detect new bioterror-associated agents, and to ensure FSIS' capability and capacity to perform the toxin and chemical testing that will be standardized across all FERN laboratories.

Fourth, the food and agriculture defense initiative will allow FSIS to participate in an interagency biosurveillance initiative that would improve the Federal government's ability to rapidly identify and characterize a potential bioterrorist attack. Funding this initiative will

improve Federal surveillance capabilities and enable FSIS to integrate with DHS to compile FSIS surveillance information rapidly with threat information. This funding would also allow FSIS to focus its resources on the vulnerable products and processes identified during the Agency's vulnerability assessments of imported and domestic products and establish a Foodborne Disease Surveillance Communication system to coordinate with DHS systems.

Because the realm of biosecurity is ever changing, FSIS must provide its workforce with the most up-to-date information possible to ensure that meat, poultry, and egg products are protected from intentional contamination. Therefore, the final component of the food and agriculture defense initiative is follow-up biosecurity training of the workforce. This additional training is essential as part of the ongoing effort to protect the public by educating the workforce regarding the latest Agency policies, threat agents, and countermeasures to those agents.

#### Public Health Training

The maturation of HACCP has widened the scope of all front-line inspection duties. While slaughter line inspectors have largely retained their traditional tasks, other front-line personnel have acquired more complex responsibilities related to public health, including food safety assessments, food security, and documentation and analysis to support detentions, recalls, or other enforcement actions.

Further integrating front-line inspection and science will allow scientifically-trained FSIS personnel to most effectively utilize their expertise. For instance, FSIS intends to fully employ the scientific skills of its Public Health Veterinarians – systems analysis, epidemiology,

biostatistics, microbiology, pathology, and toxicology – to safeguard public health. Accordingly, FSIS has been revising veterinary work assignments so that PHVs spend 25 percent of their time on public health assessment and assurance. As part of the FY 2006 budget request, FSIS is requesting an increase of \$2.2 million for relief positions so that the Agency can take full advantage of the training, experience, and responsibilities of these highly-trained PHVs. The Agency and the public will benefit from more effective utilization of the technical knowledge and skills of our veterinarians through their expanded public health activities.

#### Supporting FSIS' Basic Mission

The FSIS budget request for FY 2006 supports the Agency's basic mission of ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

In order to fulfill the Agency's statutory obligations to provide continuous inspection of meat, poultry, and egg products, the budget requests an increase of \$13.9 million for the FSIS inspection program to provide for the 2.3 percent pay raise for FSIS employees in FY 2006 and to assure that the Agency is provided sufficient funds to maintain programs without disruption to industry operations.

#### User Fee Proposal

In FY 2006, FSIS estimates it will collect \$122.9 million in existing annual user fees to recover the costs of overtime, holiday, and voluntary inspection. Of the \$849.7 million requested in the FY2006 budget, \$139 million is proposed to be derived from a new user fee that would recover

the costs of providing inspection services beyond an approved eight-hour primary shift. A legislative proposal authorizing this new fee will soon be submitted to Congress. This will result in significant savings for the American taxpayer.

### **Closing**

We will continue to engage the scientific community, public health experts, and all interested parties in an effort to identify science-based solutions to public health issues to ensure positive public health outcomes. It is our intention to pursue such a course of action this year in as transparent and inclusive a manner as is possible. The strategies I discussed today will help FSIS continue to pursue its goals and achieve its mission of reducing foodborne illness, and protecting public health through food safety and security.

Mr. Chairman, thank you again for providing me with the opportunity to speak with the Subcommittee and submit testimony regarding the steps that FSIS is taking to remain a world leader in public health. I look forward to working with you to improve our food safety system, ensuring that we continue to have the safest food supply in the world.